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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,754	10/15/2001	Roger Nitsch	P66566USO	9987
136	7590	03/04/2004	EXAMINER	
JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			CHERNYSHEV, OLGA N	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/831,754

**Applicant(s)**

NITSCH ET AL.

**Examiner**

Olga N. Chernyshev

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 42, 52, 53 and 54 have been amended and claims 55-76 have been cancelled as requested in the amendment of Paper filed on January 05, 2004. Claims 39-54 are pending in the instant application.

Claims 39-54 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on January 05, 2004 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Claim Rejections - 35 USC § 101***

5. Claims 39-54 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record in section 7 of Paper No. 12. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

Applicant traverses the instant rejection on the premises that the presently claimed protein “was discovered due to its specific function and due to its effect in the process of a particular neurodegenerative disease, i.e., Alzheimer’s disease [AD]”, and also that “[i]ts biological role and its utility as a diagnostic marker, for instance, specifically rely on its detection in connection with Alzheimer’s disease” (middle at page 25 of the Response). Applicant further submits that “the use of SELADIN-1 as a diagnostic marker in a number of applications, and the ability of making a diagnosis for a particular neurodegenerative disease, which is a very valuable and practical “real world” utility is provided” (last paragraph at page 26). These arguments have been fully considered but are not deemed to be persuasive for the following reasons.

The Examiner maintains the position that the biological role of the instant claimed SELADIN-1 protein at the time of invention has not been established. The instant specification and Applicant’s Response of January 05, 2004 fail to present any evidence of record that would clearly identify a biological activity of the instant SELADIN-1. According to legal standards, a specification can meet the requirements of utility and enablement for a new polypeptide or polynucleotide as long as the specification discloses at least one credible, specific and substantial asserted utility for the new DNA or protein encoded thereby, or a well-established utility for the claimed sequences would be *prima facie* obvious to the skilled artisan. A hypothetical example may serve to clarify. For example, a hypothetical specification discloses that a claimed polynucleotide is expressed in colon cancer and not expressed in healthy colon tissue. The hypothetical specification does not disclose the biological activity of the polypeptide encoded by the polynucleotide. The claimed polynucleotide in the hypothetical example would not be

rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as it has utility and is enabled as a colon cancer marker. However, such is not the fact pattern here. The instant specification, as filed, discloses that SELADIN-1 is expressed throughout the human brain and other human tissues of normal and AD patients and that the transcripts levels of SELADIN-1 "were significantly lower in brain regions with severe neurodegeneration" as well as that "[I]n AD brains, the expression of SELADIN-1 was substantially lower in the inferior temporal lobe compared to the frontal cortex" (page 25-26, Figures 17 and 18). Thus, there is no disclosure that the claimed polynucleotides are expressed at altered levels or forms in any specific, diseased tissue or otherwise associated with Alzheimer's disease, as implied by the instant specification. Therefore, one would reasonably conclude that based on the pattern of tissue distribution SELADIN-1 cannot be used as a marker for Alzheimer's disease and, further, one would not logically accept that biological function of Seladin-1 is related to its protective role against degeneration and cell death in general, as asserted in the instant specification.

Thus, since the instant specification does not disclose a credible "real world" use for the instant nucleic acid and encoded protein in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

#### ***Claim Rejections - 35 USC § 112***

6. Claims 39-54 are also rejected under 35 U.S.C. 112, first paragraph. Applicant's is advised that listing of claims 1, 2 and 4 in section 8 of Paper No. 12 was an obvious typographic error and that the correct claim numbers are 39-54. Because the claimed invention of claims 39-

54 is not supported by either a clear asserted utility or a well established utility for the reasons set forth in section 7 of Paper No. 12, one skilled in the art clearly would not know how to use the claimed invention.

7. Claims 40, 45 and 53 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for those reasons of record in section 9 of Paper No. 12.

Applicant argues that the instant rejection “fails to apply the correct standards for determining whether the written description requirement of § 112, ¶ 1, is satisfied with respect to a claimed genus” (end of page 27 going to page 28 of the Response). Applicant relies on case law for support of this argument (middle at page 28). These arguments have been fully considered but are not deemed persuasive because in determination if a disclosure of novel polynucleotide or polypeptide sequences satisfies the written description requirement, holdings of *Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd.*, 18 U.S.P.Q. 2d, 1016 (Fed. Cir. 1991), *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111 and *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398 (CAFC 1997) are applicable .

In *Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd.*, 18 U.S.P.Q. 2d, 1016 (Fed. Cir. 1991) the court held that:

“A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and describe how to obtain it. See *Oka*, 849 F.2d at 583, 7 U.S.P.Q. 2d at 1171. Conception does not occur unless one has a mental picture of the structure

of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated”.

Claims 40, 45 and 53 are directed to a functional variant of a nucleic acid molecule encoding a protein of SEQ ID NO: 1, the function of which is to protect cells against degeneration and/or cell death. The claims do not require that the polypeptide possess any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that is defined only by functional identity, for which no sufficient assay is disclosed.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a structure of SEQ ID NO: 1 in the form of a recitation of a “functional variant thereof”. There is not even identification of any particular portion of the structure that must be conserved.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In the decision of *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398 (CAFC 1997), the court held that:

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the



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inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1977); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious" and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ at 1966.

Thus, for reasons fully explained above, it can be concluded that claims 40, 45 and 53 are directed to subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

8. Claim 43 stands indefinite for recitation of hybridization "under stringent conditions", see reasons of record in section 12 of Paper No. 12. Applicant submits that "an example of stringent hybridization conditions is provided" on page 3 of the specification. This is not persuasive because conditions recited on page 3 are exemplary and not definitive.

9. Claim 48 recites the limitation "a plasmid" in claim 46. There is insufficient antecedent basis for this limitation in the claim, see reasons of record in section 13 as applied to claim 49, which was listed instead of 48 as a result of typographic error.

10. Claim 44 is indefinite for being dependent from indefinite claim.

***Conclusion***

11. No claim is allowed.
12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices


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published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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